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No. 94-1754

IN THE

Supreme Court of the United States

OCTOBER TERM, 1994

DOROTHY MARIE REEVES,
Petitioner,

v.

ACROMED CORPORATION
and
ST. PAUL FIRE & MARINE INSURANCE COMPANY,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

RESPONDENTS' BRIEF IN OPPOSITION TO CERTIORARI

MARSHALL G. WEAVER
ARTHUR S. PATRON, JR.
HENICAN, JAMES & CLEVELAND
111 Veterans Boulevard
Suite 1200
Metairie, Louisiana 70005
(504) 837-8080

Counsel for Respondent St. Paul Fire & Marine Insurance Company

RICHARD I. WERDER, JR.
MARK HERRMANN
(Counsel of Record)
JONES, DAY, REAVIS & POGUE
North Point
901 Lakeside Avenue
Cleveland, Ohio 44114
(216) 586-3939

Counsel for Respondent AcroMed Corporation

QUESTIONS PRESENTED

1. The federal appellate courts unanimously hold that the express preemption provision of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act preempt failure-to-warn claims brought against manufacturers of prescription medical devices. Are the First, Third, Fifth, Seventh, Eighth, and Eleventh Circuit Courts of Appeals unanimously wrong in so holding?

2. The federal appellate courts unanimously hold that there is no exception to preemption when a plaintiff alleges fraud on the United States Food and Drug Administration. Are the First, Third, and Fifth Circuit Courts of Appeals unanimously wrong in so holding?

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RESPONDENTS' BRIEF IN OPPOSITION TO CERTIORARI

Respondents respectfully request that this Court deny the petition for a writ of certiorari filed on April 24, 1995, to review the judgment of the United States Court of Appeals for the Fifth Circuit entered in this proceeding on February 10, 1995. This case presents two questions of law on which the federal appellate courts are in unanimous agreement. This case does not present the issues that petitioner identifies as having caused disagreements among the circuits.[1]

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[1] Pursuant to Rule 29.1, AcroMed Corporation does not have any parent companies or subsidiaries (other than wholly-owned subsidiaries). The parent company of St. Paul Fire & Marine Insurance Company is The

STATEMENT

Petitioner Dorothy Reeves underwent massive spinal fusion surgery to treat her "spinal stenosis with a herniated disk." Tr. at 392; *see id.* at 147. "In this case, because there were going to be five separate [vertebral] bones" involved in the surgery, Ms. Reeves' orthopedist thought "that the chances of being successful without some type of metal were very, very low." *Id.* at 397. He therefore chose to implant metal bone plates and screws as a temporary aid to healing while the five vertebrae, it was hoped, would fuse. *Id.* at 397-98. The instrumentation is "not a substitute for a bone fusion; it is an adjunct to bone fusion. It simply holds the alignment of the spine or the bones fused together. If they don't fuse for any number of different reasons, then any device will ultimately fail. They all do." *Id.* at 323.

Ms. Reeves' physician chose to use AcroMed Corporation's VSP® Bone Plates and VSP® Bone Screws in the surgery. AcroMed's bone plates and screws were cleared for sale as prescription devices by the United States Food and Drug Administration after they went through the "510(k)" pre-market notification process. Tr. 366-67; Def. Ex. 15; 21 U.S.C. § 360c(i). The 510(k) process permits a device to be marketed once the FDA determines that it is "substantially equivalent" to either a device that was sold before the Medical Device Amendments were adopted or a device that is otherwise legally being sold (a "predicate device"). 21 U.S.C. § 360c(f)(1)(A)(ii). The manufacturer submits information (including proposed labeling) to allow the FDA to compare the new device to the predicate device. 21 C.F.R. § 807.87. If both the "technological characteristics" and the labeled "intended uses" of a new device are "substantially equivalent" to a predicate device, the new device is cleared for marketing. 21 U.S.C. § 360c(i)(1)(A); 21 C.F.R. § 807.100.

St. Paul Companies, Inc. St. Paul Fire & Marine Insurance Company has no subsidiaries.

AcroMed first submitted a 510(k) notification for bone plates and screws under the label "Variable Screw Placement (VSP) Spine Plate Fixation System." Pl. Ex. 12. The FDA had trouble, not with the design but with the label, stating that there was no "pre-amendment device labeled" for spinal fixation and that using this device in the spine could pose "potential" risks different from those of other "spinal fixation systems." Pl. Ex. 16. Accordingly, the FDA declared that, labeled for spinal fixation, the bone plates and screws were "not substantially equivalent" and were not cleared for marketing under that label. *Id.*

The FDA and AcroMed then met. In December 1985, the FDA suggested to AcroMed that the labeling be changed to delete any reference to the spine, and that AcroMed should then re-submit 510(k) notifications for devices labeled simply as "bone plates" and "bone screws." Tr. 360-61. This suggestion was fully consistent with the FDA's long-standing policy and practice of permitting "off-label" uses of medical devices. *See, e.g.*, 37 Fed. Reg. 16503 (Aug. 15, 1972); *FDA Drug Bull.*, Vol. 12, No. 1 at pp. 4-5 (Apr. 1982). Under the FDA's suggestion, the devices would then be available to those physicians who chose, in the exercise of medical judgment, to prescribe it for the spine in various "off-label" uses. Tr. 443. AcroMed's representatives "followed appropriate FDA procedures and even advice in filing for approval under the alternative applications." *Gosserand v. Buckman Co.*, No. C-90-0542, slip op. at 10 (N.D. Cal. May 31, 1991).

AcroMed was "under no legal or regulatory obligation to discourage off-label" use of its products "or to legitimize unapproved indications by pursuing FDA approval." *U.S. Regulatory Reporter* 3 (June 1989). AcroMed nonetheless wanted the right to sell its devices labeled specifically for use in the spine. AcroMed thus also submitted to the FDA an application to conduct a clinical trial of its devices pursuant to an Investigational Device Exemption. 21 C.F.R. § 812.20; Pl. Ex. 18.

Once that clinical trial was approved, AcroMed's plates and screws were on the market with dual labeling. They were available generally when labeled as "bone screws" and physicians could use them as they saw fit. Identical screws, labeled as "pedicle screws," were available only to clinical investigators and could be used only according to a strict investigational protocol. This dual labeling is not uncommon; indeed, Congress anticipated it when enacting the Medical Device Amendments. *See* H.R. Rep. No. 853, 94th Cong., 2d Sess. at 14-15 (1976).

Ms. Reeves' surgery initially seemed to have worked, despite the four to one odds against it. Tr. at 394 (20 percent success rate). X-rays taken two years post-operatively showed nothing wrong with the plates or screws. *Id.* at 400, 403 & 406. At that time, Ms. Reeves' orthopedic surgeon "offered to take out [Ms. Reeves'] plates, because sometimes we took them out, and she stated that she didn't want them taken out." *Id.* at 400. The plates and screws had thus survived for their intended lifespan.

Ms. Reeves was unhappy, however, with the lingering pain in her back. On December 27, 1991, nearly six years after her surgery, Ms. Reeves filed a product liability complaint against AcroMed and its insurance carrier, St. Paul Fire & Marine Insurance Company. In January 1993 — fully seven years after Ms. Reeves' surgery — a new orthopedist took x-rays and found that two of the AcroMed screws implanted as part of Ms. Reeves' operation had broken. Tr. at 149. In addition, however, according to Ms. Reeves' own expert witness, her surgery had not succeeded: Of the many vertebral levels involved, "[s]he has no fusion" at the two lowest ones. *Id.*

On these facts, a jury awarded a verdict against AcroMed. On appeal, the Fifth Circuit vacated the judgment because Ms. Reeves' failure-to-warn claim was preempted under federal law. The Fifth Circuit remanded for a new trial of the claim that AcroMed's devices are unreasonably dangerous *per se*. After the Fifth Circuit denied rehearing, Ms. Reeves filed this petition for a writ of certiorari.

ARGUMENT

This case presents two issues: (1) Do the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act preempt a failure-to-warn claim brought against a manufacturer of a prescription medical device? (2) Is there an exception to preemption of failure-to-warn claims if a plaintiff pleads that a manufacturer defrauded the FDA? Following unanimous federal appellate authority, the Fifth Circuit answered the first question in the affirmative and the second in the negative. There is no conflict in the circuits.

Even if this Court were to accept petitioner's suggestion and become interested in medical device preemption in the abstract, this case is a poor candidate for certiorari. First, this case presents only the issue of preemption of failure-to-warn claims; most medical device cases raise broader preemption questions, including claims of manufacturing defect, design defect, implied and express warranty, negligence *per se*, or others. Preemption of these other claims — as to which petitioner asserts that the circuits are divided — is simply not presented on this record.

Moreover, this case involves the "off-label" use of a medical device; most cases involve situations where devices are used for their labeled indications. This Court should not invest its limited resources hearing a case that involves atypical facts. Finally, this case has been remanded for a new trial of one remaining claim. Even if this particular case ultimately merited review, there is no reason to grant certiorari today.

Accordingly, neither the issue presented here, nor the particular case involved, merits granting certiorari.

I. THE FIFTH CIRCUIT FOLLOWED UNANIMOUS FEDERAL APPELLATE AUTHORITY IN FINDING THAT THE MEDICAL DEVICE AMENDMENTS PREEMPT FAILURE-TO-WARN CLAIMS BROUGHT AGAINST MANUFACTURERS OF PRESCRIPTION MEDICAL DEVICES.

Federal law is "the supreme Law of the Land." U.S. Const. art. VI, cl. 2. State laws that conflict with federal laws and regulations are, therefore, preempted. *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992). An express preemption provision bars failure-to-warn claims brought against manufacturers of prescription medical devices. 21 U.S.C. § 360k(a).

The federal regulatory scheme gives the FDA vast power over manufacturers of medical devices, including civil and criminal enforcement powers. 21 U.S.C. §§ 332-34 & 337. That federal regulation displaces much state or private regulation in the field. "[A]ll . . . proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337. Congress chose to give the FDA exclusive enforcement power to ensure "that innovations in medical device technology are not stifled by unnecessary restrictions." H.R. Rep. No. 853, 94th Cong., 2d Sess. at 12.

To achieve that goal, Congress included in the Medical Device Amendments an express preemption provision:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In addition to the statutory preemption provision, the FDA regulations contain a second provision that relates specifically to product labels:

> Where [a state or local] prohibition has the effect of establishing a substantive requirement for a specific device, *e.g.*, a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act.

21 C.F.R. § 808.1(d)(6)(ii).

In its implementing regulations, the FDA has declared that preemption applies equally whether the State is acting "by statute, ordinance, regulation, or court decision." 21 C.F.R. § 808.1(b). Preemption applies wherever the FDA "has established specific counterpart regulations [to the challenged state requirements] or there are other specific requirements applicable to a particular device under" the federal Act. 21 C.F.R. § 808.1(d).[2]

The regulatory structure applicable to AcroMed's devices "involves the FDA in considerable oversight regarding proposed package labeling." *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993). When AcroMed sought clearance of its bone plates and bone screws, it was required to submit to the FDA "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use." 21 C.F.R. § 807.87(e). If the FDA is not satisfied with a submission, it can require the

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[2] This regulation goes on to say that the Medical Device Amendments do not preempt state law requirements "that are equal to, or substantially identical to," the federal requirements. 21 C.F.R. § 808.1(d)(2). There is no guarantee, however, that a lay jury will interpret state negligence law to match precisely the nuances of the federal regulations. That is why the federal appellate courts have unanimously held that state law negligence and strict liability claims for failure to warn are preempted. *See* cases cited in text accompanying note 4 *infra*.

manufacturer to submit "[a]ny additional information" it deems necessary. 21 C.F.R. § 807.87(h).

The labeling for "prescription devices" like AcroMed's products is subject to particularly intensive regulation. Tr. 440; 21 C.F.R. § 801.109. Because the labels on prescription devices are seen only by physicians, not by ordinary consumers, they are subject to strict and specific FDA requirements imposing obligations to disclose their uses, hazards, contraindications, side effects, and precautions. 21 C.F.R. § 801.109(c).

Once the devices are cleared, the labeling remains subject to monitoring by the FDA. The FDA receives reports from all manufacturers whose devices may have contributed to a death or serious injury. 21 C.F.R. § 803.1. If those reports suggest the need for remedial action, the FDA can require "relabeling." 21 C.F.R. § 803.3(g). The manufacturer cannot add significant new claims to its labeling without obtaining new FDA clearance. 21 C.F.R. § 807.81(a)(3). If the FDA believes that a danger to public health "can be corrected or eliminated by labeling or a change in labeling," the Commissioner has broad power to require those changes. 21 C.F.R. § 895.25(a).[3]

Given this extensive control over the contents of prescription device labeling, the federal appellate courts have unanimously held that failure-to-warn claims are preempted when brought against manufacturers of prescription medical devices. *See Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir. 1995) (device subject to pre-market approval; failure-to-warn claim preempted); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994)

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[3] Petitioner cites *Freightliner Corp. v. Myrick*, No. 94-286, 1995 WL 224617 (U.S. Apr. 18, 1995), for the proposition that the National Highway Traffic Safety Administration's failure to regulate does not constitute implicit regulation. Pet. at 22. *Freightliner* has no bearing here, where AcroMed's products were actually regulated under both the 510(k) clearance process and the specific regulation dictating the contents of labeling on prescription devices. 21 C.F.R. §§ 801.109 & 807.87.

(device subject to pre-market approval; failure-to-warn claim preempted); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542-43 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994) (device used in clinical trial; failure-to-warn claim preempted); *Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994) (device subject to pre-market notification; failure-to-warn claim preempted); *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994) (device used in clinical trial; failure-to-warn claim preempted); *Stamps*, 984 F.2d 1416 (device subject to pre-market approval; failure-to-warn claim preempted); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993) (device subject to pre-market approval; failure-to-warn claim preempted); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1334 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992) (device used in clinical trial; failure-to-warn claim preempted). Indeed, the only two federal circuit courts to address the question have held that failure-to-warn claims are preempted even when brought against manufacturers of Class II *non*-prescription devices. *See National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988 (8th Cir. 1994); *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989).[4]

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[4] Two federal appellate courts have recognized that "[i]n promulgating the MDA, Congress expressly intended to preempt state tort law," but found preemption inapplicable to claims against materials or entities not subject to FDA regulation. *Anguiano v. E.I. Du Pont de Nemours & Co.*, 44 F.3d 806, 809 (9th Cir. 1995); *see Lamontagne v. E.I. Du Pont de Nemours & Co.*, 41 F.3d 846, 855 (2d Cir. 1994) (involving same product). In the words of the Ninth Circuit: "The district court concluded that [Teflon] is not a medical device and, accordingly, is not subject to the requirements of the MDA. We agree." *Anguiano*, 44 F.3d at 811. The federal trial court decisions on preemption reach conflicting results. *See Bravman v. Baxter Healthcare Corp.*, 842 F. Supp. 747 (S.D.N.Y. 1994) (collecting cases). No state supreme court has yet addressed the issue of preemption of a failure-to-warn claim. *Cf. Larsen v. Pacesetter Sys., Inc.*, 837 P.2d 1273 (Haw.), *amended*, 843 P.2d 144 (Haw. 1992) (finding only implied warranty claim not preempted).

The appellate courts are arguably divided over the scope of preemption as to claims of manufacturing defect, design defect, and express warranty. Those issues, however, are not presented here. If a need arises to resolve the conflicts petitioner identifies as to preemption of other claims, the Court will undoubtedly have the opportunity to address those issues in a case that actually presents them. This Court should not grant certiorari in a case involving only failure-to-warn preemption, an issue on which the federal appellate courts have reached unanimous agreement.[5]

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[5] Petitioner seeks to distinguish the preemptive effect of pre-market approval from the preemptive effect of pre-market notification under section 510(k). She argues that clearance under section 510(k) "does not in any way denote approval of the device and it is misbranding to claim otherwise." Pet. at 5. But the FDA does not allow the manufacturer of *any* device, however it was cleared or approved for marketing, to tout its product as "FDA-approved." Federal law prohibits "[t]he using, on the labeling of any drug or device or in any advertising relating to such drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect." 21 U.S.C. § 331(*l*). Petitioner's suggested distinction is of no consequence.

Similarly, petitioner cites 21 U.S.C. § 360h as evidence of a Congressional intent to retain common law liability. Pet. at 15 n.5. But section 360h applies only to damages sustained by health care providers as a result of an FDA order to recall a device. 21 U.S.C. § 360h(b), (c) & (e). No recall order was involved here.

Petitioner also suggests that "*several* intermediate appellate decisions in the State systems" have held that the Medical Device Amendments do not preempt any state law tort claims. Pet. at 27 (emphasis added). This is surely an unfortunate string of typographical errors; in fact, *one* intermediate appellate decision has so held, and it has been accepted for review by the Illinois Supreme Court. *Haudrich v. Howmedica, Inc.*, 642 N.E.2d 206 (Ill. App. Ct. 1994), *app. pending* (Ill. Feb. 1, 1995).

II. THE FIFTH CIRCUIT FOLLOWED UNANIMOUS FEDERAL APPELLATE AUTHORITY IN FINDING THAT THERE IS NO FRAUD-ON-THE-FDA EXCEPTION TO PREEMPTION.

The federal appellate courts have also unanimously agreed that claims of fraud on the FDA (or the lesser offense of negligent non-compliance with FDA regulations) do not create an exception to preemption. This issue also does not merit granting certiorari.

If a manufacturer defrauds the FDA, the FDA can pursue criminal penalties. 21 U.S.C. §§ 331(a)(2) & 333(a)(2). The FDA has made clear that it will take action against anyone who defrauds it. 56 Fed. Reg. 46,191, 46,199-200 (Sept. 10, 1991). If a manufacturer defrauds the FDA, "it is for the FDA to remedy that situation using the authority Congress gave it in the [Medical Device Amendments]." *Michael*, 46 F.3d at 1329. Accordingly, the federal appellate courts have unanimously held that there is no exception to preemption where a plaintiff pleads fraud on the FDA. *Id.*; *King*, 983 F.2d at 1140.

The Fifth Circuit refused "to create an unwieldy exception to [federal preemption] in cases where manufacturers attempt to mislead the FDA or violate FDA regulations." Pet. App. at A16. Petitioner argues that this holding "is directly in conflict with the Third Circuit's ruling in *Michael* [and] the Eighth Circuit's decision in *National Bank of Commerce*." Pet. at 25. This is wrong. As the Fifth Circuit noted:

> Other courts have questioned the applicability of preemption in cases where a manufacturer has violated FDA regulations. However, most of the statements favoring an exception to preemption under these circumstances are in dicta. [Citations omitted.] [A]s of the date of this opinion, no court has squarely held that a violation of FDA labeling regulations defeats preemption of state failure-to-warn claims.

Pet. App. at A16 n.4. This analysis holds true for both *National Bank of Commerce* and *Michael*. *National Bank of Commerce*, 38 F.3d at 999 ("FDA did in fact determine that Kimberly-Clark's

labels comply with § 801.430."); *Michael*, 46 F.3d at 1329 ("Under the MDA, states have no authority to police Shiley's compliance with the FDA's procedures.").[6]

The FDA is expert in interpreting its rules and regulations. It has ample power to punish those who defraud it or do not comply with its regulations. This Court should not grant certiorari to review the unanimous holding of the federal appellate courts that there is no exception to preemption where a plaintiff pleads a claim of fraud on the FDA.

III. THE NARROW ISSUE AND ATYPICAL FACTS INVOLVED HERE MAKE THIS CASE UNWORTHY OF REVIEW.

Finally, if this Court were inclined to address the issue of medical device preemption in the abstract, this case would still be a poor candidate for certiorari.

First, petitioner concedes that many of the conflicts in the law that she identifies are not "presented by the Fifth Circuit's decision in the instant case." Pet. at 27. For example, she argues that the First Circuit's decision in *King* holds that claims for "breach of express warranty are preempted with respect to devices which have received pre-market approval while the Third Circuit's decision in *Michael* holds that express warranty . . . claims are not preempted." *Id.* This case, however, does not involve an express warranty claim.

Similarly, petitioner argues that "language used by the Ninth Circuit in *Anguiano* implies that tort claims with respect to any device cleared for market[ing] as a Class III device are preempted while other decisions appear to hold that pre-market approval is a prerequisite to across the board preemption of tort claims for

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[6] *National Bank of Commerce* and *Michael* both *held* that failure-to-warn claims were in fact preempted. *National Bank of Commerce*, 38 F.3d at 999; *Michael*, 46 F.3d at 1324. Those cases cannot even theoretically create a conflict with the Fifth Circuit's identical holding here.

Class III devices." *Id.* This case, however, does not involve a Class III device at all. If this Court ultimately decides to address the question of medical device preemption, it should select a case that squarely presents the relevant issues.

Moreover, petitioner urged in the Fifth Circuit that preemption does not apply to AcroMed's devices because the physician chose to put them to an "off-label" use. Although we believe that distinction to be irrelevant, it is true that most medical device products liability cases do not involve the "off-label" use of a device. If this Court ultimately decides to address the question of medical device preemption, it should select a case that involves the use of a device for a labeled indication, so that the Court's holding would squarely govern a broader universe of cases.

Finally, the Fifth Circuit vacated the trial court judgment and remanded for a new trial of the claim that AcroMed's devices are unreasonably dangerous *per se*. Pet. App. at A-19. On remand, AcroMed may argue that this claim, too, is preempted. In any event, this very case may yet return to this Court sometime in the future, after the preemption issue has better developed in the lower courts. There is no reason to grant certiorari today.

This case prematurely presents a narrow question of law on idiosyncratic facts. The Court should not grant certiorari.

CONCLUSION

Petitioner asks this Court to address two issues on which the federal appellate courts are in unanimous agreement. If these issues ever merit review, the vehicle should not be a case that presents only a very narrow form of the preemption question in the context of off-label use. Accordingly, the Court should deny the petition for certiorari.

Respectfully submitted,

MARSHALL G. WEAVER
ARTHUR S. PATRON, JR.
HENICAN, JAMES & CLEVELAND
111 Veterans Boulevard
Suite 1200
Metairie, Louisiana 70005
(504) 837-8080

Counsel for Respondent St. Paul Fire & Marine Insurance Company

RICHARD I. WERDER, JR.
MARK HERRMANN
(Counsel of Record)
JONES, DAY, REAVIS & POGUE
North Point
901 Lakeside Avenue
Cleveland, Ohio 44114
(216) 586-3939

Counsel for Respondent AcroMed Corporation

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